DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: Macroplastique Implants
Docket Nos.: FDA-2008-E-0091
FDA-2008-E-0099
FDA-2008-E-0204

JAN 22 2009

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 5,258,028; 5,336,263; and 5,571,182, filed by Uroplasty, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for Macroplastique Implants, the medical device claimed by the patents.

The total length of the regulatory review period for Macroplastique Implants is 2,651 days. Of this time, 1,973 days occurred during the testing phase and 678 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act involving this device became effective: July 30, 1999.

   The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on June 30, 1999. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on July 30, 1999, which represents the IDE effective date.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: December 22, 2004.

   The applicant claims December 21, 2004, as the date the premarket approval application (PMA) Macroplastique Implants (PMA P040050) was initially submitted. However, FDA records indicate that PMA P040050 was submitted on December 22, 2004.

3. The date the application was approved: October 30, 2006.

FDA has verified the applicant's claim that PMA P040050 was approved on October 30, 2006.

This determination of the regulatory review period by FDA does not take into account the effective date of the patents, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc:
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